

THE BERNARD M. BARUCH COLLEGE

OF

THE CITY UNIVERSITY OF NEW YORK

17 LEXINGTON AVENUE • NEW YORK, N. Y. 10010

673-7700

DEPARTMENT OF STATISTICS

November 30, 1971

Mr. Allan Topol
Covington & Burling
888 Sixteenth Avenue N.W.
Washington, D.C.

Dear Mr. Topol:

In accordance with your request, I have analyzed the data on nicotine and tar (TPM Dry) determinations performed by the Federal Trade Commission laboratory as contrasted with the equivalent data produced by the Tobacco Industry Testing Laboratory.

The data involved were obtained from the FTC laboratory summary sheets and the reports of the TITL for tests 5 through 9.⁽¹⁾ It is my understanding that for brand cigarettes, the samples to be tested are picked up simultaneously for both the FTC laboratory and TITL. Thus the sample cigarettes used at both laboratories are reasonably comparable reflecting only the sampling variability to be expected within the overall sample. The analysis given below is based on the validity of this assumption.

⁽¹⁾ The dates of the test were; Test 5, July 9, 1969, Test 6, November 19, 1969, Test 7, May 18, 1970, Test 8, October 21, 1970 and Test 9, August 1971.

PM3001013704

Page 2
Mr. Allan Topol
November 30, 1971

I. COMPARATIVE TAR (TPM DRY) AND
NICOTINE LEVELS

The current test showed an appreciably higher average tar (TPM Dry) for brand cigarettes for the FTC laboratory results than for the TITL determinations for all brands listed by both laboratories.

Further, the last three tests have shown a tendency for the FTC average tar to be higher than that for TITL for the branded cigarettes, although previously in test 5 they were identical.⁽²⁾

Average Tar (TPM Dry)
FTC and TITL Laboratory Determinations
For Brand Cigarettes
Tested by Both Laboratories
Tests 5 Through 9

<u>Test Number</u>	<u>Date</u>	<u>Average Tar TPM Dry, mgm</u>		<u>Difference</u>	<u>Number of Brands</u>
		<u>FTC</u>	<u>TITL</u>		
5	7/9/69	19.558	19.609	+0.051	118
6	11/19/69	19.132	19.255	+0.123	119
7	5/18/70	18.770	18.395	-0.375	116
8	10/21/70	18.738	18.637	-0.101	118
9	8/71	18.881	18.052	-0.829	121

(2) Due to the large amount of calculations which would have been necessary to perform tests of statistical significance for each test from 5 through 9, no tests of significance were performed for the difference.

PM3001013705

Page 3
Mr. Allan Topol
November 30, 1971

This tendency for the FTC tar determinations to run higher than that for the TITL is confirmed by differences in average TPM Dry for the monitor cigarettes.

However, in making the comparison, the data for the monitor cigarettes for test 9 cannot be compared because different monitor cigarettes were used by the two laboratories. In the comparable tests (5 through 8) where the same monitor cigarettes were used, all showed a higher TPM average for the FTC laboratory determinations than for TITL.

Average Tar (TPM Dry)
For Monitor Cigarettes
by FTC and TITL Laboratory Determinations

Test Number	Date	Average Tar TPM Dry		Differ- ence***	Number of Determin- ations		Type of Monitor	
		FTC	TITL		FTC	TITL	FTC	TITL
5	7/9/69	20.13	19.79	-.34**	823	631	Amer	Amer
6	11/19/69	20.25	20.03	-.22**	835	639	Amer	Amer
7	5/18/70	20.59	19.81	-.78**	797	631	Amer	Amer
8	10/21/70	18.52*	18.37*	-.15**	832	630	B&W	B&W
9	8/71	(19.71)	(18.13)	*	1138	693	L&M	B&W

*No comparison possible due to different monitors used at each laboratory.

**All differences statistically significant at better than the .01 level.

***Negative difference indicates lower value for TITL and higher for FTC.

PM3001013706

Page 4
Mr. Allan Topol
November 30, 1971

An analysis of the differences in TPM (Dry) determinations for the various brands disclosed that in the current test, the disparity increases with the level of tars in the cigarettes tested, with FTC laboratory results producing higher levels in all categories.

Differences in Average TPM (Dry)
FTC Laboratory and TITL Determinations
For Brand Cigarettes
By FTC TPM Levels
Test Dated August 1971 Test No. 9

<u>FTC TPM (Dry), mgm</u>	<u>Difference* FTC and TITL Average TPM (Dry), mgm</u>	<u>Number of Brands</u>
1 - 16.9	-.27	30
17.0 - 19.9	-.54	52
20.0 - 22.9	-.63	17
23.0 and over	-2.67	22

NOTE: Only for brands tested by both laboratories.

*Negative differences indicate a lower average value for TITL and higher for FTC.

A statistical test⁽³⁾ discloses that these differences between the averages at the different FTC TPM (Dry) levels is statistically significant and thus the trend is not an accident of sampling.

⁽³⁾ An analysis of variance test discloses that the variation in the average difference among the FTC level groups are statistically significant at better than .001 level.

Page 5
Mr. Allan Topol
November 30, 1971

This tendency for an increasing disparity between the FTC and TITL determinations has developed recently. The disparities between the average determinations in prior tests are shown below:

Differences in Average TPM (Dry)
FTC Laboratory and TITL Determinations
for Brand Cigarettes
By FTC TPM Levels
Tests 5 Through 9

FTC TPM Dry mgm	Difference* FTC & TITL Averages TPM (Dry) Tests					Number of Brands Tests				
	5	6	7	8	9	5	6	7	8	9
1-16.9	-.32	-.15	-.47	-.06	-.27	25	32	28	27	30
17.0-19.9	+.07	+.07	-.42	-.05	-.54	33	35	37	45	52
20.0-22.9	+.05	+.07	-.50	-.11	-.63	39	28	30	24	17
23.0 and over	+.52	+.61	.00	-.21	-2.67	23	24	21	22	22

*Negative difference indicates higher FTC average and lower TITL average.

It is to be noted that no such consistent difference is found in the nicotine determinations by the two laboratories. The average nicotine determinations for monitor cigarettes for the two laboratories indicate these inconsistent differences.

PM3001013708

Page 6
Mr. Allan Topol
November 30, 1971

Average Nicotine
FTC Laboratory and TITL Determinations
For Monitor Cigarettes
Tests 5 Through 9

Test Number	Date	Average Nicotine mgm		Differ- ences*	Number of Determin- ations		Type of Monitor	
		FTC	TITL		FTC	TITL	FTC	TITL
5	7/9/69	1.330	1.298	-.032	823	631	Amer	Amer
6	11/19/69	1.310	1.279	-.031	835	639	Amer	Amer
7	5/18/70	1.291	1.323	+.032	797	631	Amer	Amer
8	10/21/70	1.267	1.255	-.012	832	630	B&W	B&W
9	8/71	1.391**1.269**		-	1138	693	L&M	B&W

*Negative difference indicates higher value for FTC, lower value for TITL.

**Not comparable since different monitor cigarettes were used at each laboratory.

Nevertheless, it is to be noted that these differences though small, are all statistically significant and not an accident of sampling. For tests (5 through 8), in which the same monitors were used in both laboratories, the overall average nicotine average for the FTC laboratory of 1.300 mgm compares to the TITL laboratories average of 1.288 mgm.

PM3001013709

Page 7
Mr. Allan Topol
November 30, 1971

The TPM (Dry) value is calculated from 3 separately determined values; TPM (Wet), Water and Nicotine. The water and nicotine values are subtracted from the TPM (Wet) to obtain the TPM (Dry). Since these values are established separately, a study of the disparities between the two laboratories for these three types of determinations may disclose the reason for the above noted differences in TPM (Dry) values.

It will be remembered that there is a trend in the interlaboratory differences in TPM (Dry) when tabulated by FTC values for TPM (Dry) for test 9 data. The first analysis attempted to establish reasons for these differences by contrasting the interlab disparities for determinations of TPM (Wet), water and nicotine separately for high "tar" cigarettes (23 mgm and over of TPM (Dry) - FTC values) and low "tar" cigarettes (1 - 16.9 mgm TPM (Dry) - FTC values). The comparison of the averages for the two laboratories is given below:

PM3001013710

Page 8
Mr. Allan Topol
November 30, 1971

Average TPM(Wet), Nicotine and Water
High and Low "Tar" Brand Cigarettes
As Determined by FTC Laboratory and TITL
Test No. 9 Dated August 1971

FTC TPM Dry mgm	Average mgm* TPM (Wet)			Average mgm* Water			Average mgm* Nicotine		
	FTC	TITL	Diff.	FTC	TITL	Diff.	FTC	TITL	Diff.
1-16.9	14.40	14.42	+	1.71	1.97	+	.74	.77	+
23 and over	32.69	29.50	-3.19	3.94	3.44	-.50	1.60	1.59	+.01

*Average mgm per cigarette. The low tar cigarettes included 30 brands, the high tar 22 brands.

NOTE: Negative differences indicate a higher FTC value and lower TITL value.

The outstanding comparison is in the TPM (Wet) values where the disparity between the averages for the two laboratories differed widely for high and low "tar" cigarettes but showed virtually no difference for the low "tar" cigarettes.

It might be expected that with higher TPM (Wet) averages at the FTC laboratory for high "tar" cigarettes, that the water determinations would tend to be higher, which indeed they were. For low tar cigarettes the amount of water was actually lower at the FTC laboratory.

PM3001013711

Page 9
Mr. Allan Topol
November 30, 1971

However, when the water content is expressed as a percent of the TPM (Wet), it is seen that this water content is disproportionate to the TPM (Wet) values at the two laboratories.

Relative Water Content of TPM (Wet)
High and Low "Tar" Brand Cigarettes
As Determined by FTC Laboratory and TITL
Test No. 9 Dated August 1971

FTC TPM Dry mgm	Water Content As Percent of TPM (Wet)		Diff.
	FTC	TITL	
1 - 16.9	11.9%	13.7%	-1.8%
23 and over	12.1%	11.7%	+ .4

Thus, the difference between the two laboratories in TPM (Wet) for high "tar" cigarettes is not completely offset by the increase in water content.

The nicotine determinations at the two laboratories were very close as shown above and have been very close during prior tests.

PM3001013712

Page 10
Mr. Allan Topol
November 30, 1971

Average Nicotine Determinations
As Determined by FTC Laboratory and TITL
For High "Tar" Brand Cigarettes
Test 5 Through 9

Test	Average Nicotine Per Cigarette mgm.		Diff.	No. of Brands
	FTC	TITL		
5	1.68	1.67	-.01	30
6	1.60	1.59	-.01	24
7	1.58	1.63	+.05	21
8	1.62	1.63	+.01	22
9	1.60	1.59	-.01	22

Apparently the bulk of the disparity lies in the greater TPM (Wet) at the FTC laboratory for high "tar" cigarettes. Since the TPM (Wet) is determined merely by subtracting the weight of the filter before and after smoking, the disparity may well lie either in the operation of the smoking machines or the smoking conditions.

An analysis of the average number of puffs per cigarette smoked for the same high and low "tar" cigarettes indicated that the average number of puffs per cigarette was higher for TITL determinations in Test 9 than for FTC with a greater disparity for the high "tar" cigarettes.

Page 11
Mr. Allan Topol
November 30, 1971

Average Puffs Per Cigarette
High and Low "Tar" Brand Cigarettes
For FTC Laboratory and TITL
Test No. 9 Dated August 1971

FTC TPM Dry mgm	Average Puffs Per Cigarette		<u>Difference</u>
	<u>FTC</u>	<u>TITL</u>	
1 - 16.9 23 and over	7.85	8.10	+ .25
	9.18	9.59	+ .41

This finding is reinforced by the fact that for all 30 brands of low "tar" cigarettes and all 24 brands of high "tar" cigarettes, the average number of puffs for every brand was higher at TITL than at the FTC laboratory. This established the statistical significance of the differences in average puffs without question!

Among other possible reasons, the difference in average puffs for the two laboratories can be ascribed to differences in speed of the smoking machines, differences in vacuum, difference in conditioning of the cigarettes and differences in laboratory humidity conditions.

PM3001013714

Page 12
Mr. Allan Topol
November 30, 1971

If the independent listing by TITL as well as FTC is to serve any real purpose, it is important that the two laboratories be standardized insofar as possible. It is evident that some, if not all of the differences can be ascribed to one or more of the factors mentioned above and largely arise from differences in TPM (Wet).

To this end, it is suggested that if FTC cooperation can be secured, that:

1. A careful check on the smoking machine operations be made on a comparative basis at both laboratories including machine speed and vacuum draw.
2. Interchange tests be performed on the moisture content of samples of cigarettes prior to smoking as well as tests of humidity conditions at the two laboratories.
3. The present monitor cigarettes be changed to high TPM (Dry) type cigarettes with such TPM (Dry) values in excess of 25 mgm per cigarette since those monitors will be more sensitive to differences.
4. Continuing comparative analyses of all determinations including TPM (Wet), water content and nicotine be conducted for all tests in the future.

PM3001013715

Page 13
Mr. Allan Topol
November 30, 1971

II. COMPARATIVE VARIABILITY IN DETERMINATIONS

It is not possible to establish which of the laboratories is more nearly correct in its nicotine and TPM determinations based on smoking machine operations, since there is no standard to which the result can be compared, but some measure of the quality of the laboratory work can be gleaned from the available data.

A measure of the quality of performance of a laboratory is the stability of repeated determinations from aliquots of a given material. The laboratory that produces more uniform (less variable) results for a given substance from which the aliquots were taken.

However, in the case of nicotine and TPM (Dry) determinations based on smoked cigarettes, the samples are not from a uniform well mixed solution, so that the variability of the determinations is also a function of the variability of the cigarettes tested.

PM3001013716

Page 14
Mr. Allan Topol
November 30, 1971

A comparative situation is obtained for the FTC laboratory and TITL results in the tests of monitor cigarettes where both laboratories are smoking from a batch of relatively uniform cigarettes. The comparative variability of the results as measured by the standard deviation of the determinations should then be reflective of the comparative quality of the performance.

However, the FTC laboratories follow the practice of discarding extreme or unusual values. These discards are very numerous. The number of discards indicated on the FTC summary sheets by being crossed out or by being marked 'discarded'⁽⁴⁾ for tests 5 through 9 are shown below.

Nicotine and TPM Determinations
Discarded on FTC Summary Sheets
Tests 5 Through 9

<u>Test Number</u>	<u>Monitor Cigarettes</u>	<u>Brand Cigarettes</u>	<u>Total</u>
5	77	6	139
6	19	72	91
7	94	272	366
8	17	76	93
9	158	232	390

⁽⁴⁾ This count does not include figures omitted without explanation nor those discarded as lost or those listed on the detailed calculation sheets but not on the summaries.

PM3001013717

Page 15
Mr. Allan Topol
November 30, 1971

Reportedly, the discards are the result of a statistical outlier test but since, in some cases, particularly in the monitor results, entire groups or runs are discarded, this statistical technique may not have been used in all situations. The desirability of this practice from a statistical viewpoint will be discussed later. I have been informed⁽⁵⁾ that the TITL does not follow the practice of eliminating extreme values but uses all results.

As a result, the discards of unusual values among the determinations should result in greatly lowered variability for FTC determinations since the remaining values should then be much more uniform than those of TITL. However, this is not the case as may be seen in the comparative standard deviations of tar and nicotine determinations from uniform batches of monitor cigarettes used at both laboratories shown below. Again, it is to be noted that

⁽⁵⁾ I was informed by telephone by Dr. Steel that the practice followed at the FTC laboratory of discarding extremes is not used by TITL.

Page 16
Mr. Allan Topol
November 30, 1971

since the same monitor cigarettes were not used at both laboratories for test 9, any comparison for that test is dubious.

The variability of determinations for monitor cigarettes provide the best comparison between the laboratories since they both used cigarettes from the same factory batch and the determinations were very numerous.

Standard Deviation
of TPM (Dry) and Nicotine Determinations
of Monitor Cigarettes

Standard Deviation*					
Test Number	Date	TPM (Dry)		Nicotine	
		FTC	TITL	FTC	TITL
5	7/9/69	.7473	.8049	.0506	.1047
6	11/19/69	.7784	.8972	.0737	.0527
7	5/18/70	.9654	.7490	.0799	.0519
8	10/21/71	1.1734	.7954	.0615	.0614
9	8/71	.8612**	.7536**	.0547**	.0612**

*The standard deviations are the overall standard deviations for all determinations regardless of date performed. It measures the overall variability of the determinations.

**These standard deviations cannot be compared between the laboratories since different monitor cigarettes were used at each laboratory.

PM3001013719

Page 17
Mr. Allan Topol
November 30, 1971

The average standard deviation of the TPM (Dry) determinations for comparable tests (5 through 8) for FTC laboratory was .9161 while at TITL it was .8116. The average standard deviation for the same four tests (5 through 8) for nicotine was .0664 for the FTC laboratory and .0677 for TITL. These figures do not reflect the much greater uniformity in FTC determinations that should be expected as a result of the extensive discards noted previously. Thus, there is an implication that the TITL determinations would show a much lower variability than those for the FTC, if such discards were not eliminated.

III. DISCARDS

The FTC practice of discarding unusual values, even if based on a statistical outlier test is of dubious validity. Outlier tests are of great value and elimination of the results are justified when a uniform sample is tested, as in aliquots of a well mixed solution. Thus if an outlier is determined by a statistical test among determinations for aliquots from a well mixed solution, the discard of such

PM3001013720

Page 18
Mr. Allan Topol
November 30, 1971

a value is justified on the basis that this is a reflection of a failure in the laboratory measurement techniques or an error in recording such results.

However, in testing cigarettes, the inherent variability of the cigarettes, even within cigarettes from the same carton and much more so from different purchased cartons contained within the overall sample, is very great.

Not only is there the variability induced by the inherently variable agricultural product (tobacco) but the innumerable variations in manufacture, as well as time to sale, cause great variations in the determinations. Thus older and more dried out cigarettes smoke faster. The cigarettes of necessity may vary considerably in weight reflecting differences in the amounts of tobacco in individual cigarettes. The diameters vary effecting smoking speed. Pinholes may occur in the cigarette paper, filters may vary, etc.

PM3001013721

Page 19
Mr. Allan Topol
November 30, 1971

Thus it is to be entirely expected that individual unusual results may arise for determinations of TPM and nicotine which in no way reflect variations in the measurements, but rather expected variations in the cigarettes. Since the consumer uses the cigarettes as received regardless of variation, there is no sound justification for discarding the resulting figures.

This is especially true of brand cigarettes where only 20 determinations are usually used for the average. Yet, in achieving these 20 values, in some instances as many as 5 or 6 determinations were dropped. This is an extremely dubious practice.

It is suggested that the issue of the practice by the FTC laboratory of extensive elimination of values be raised as questionable. It is to be noted that even the large number of such discards shown in the table given previously do not reflect all the eliminated data but just those crossed out or marked discarded on the summary sheets.

PM3001013722

Page 20
Mr. Allan Topol
November 30, 1971

IV. MONITOR CIGARETTES

One of the most important protective features for the integrity of the data from both laboratories are the comparison between laboratories of the results for monitor cigarettes. These, if properly handled, represent a relatively well mixed uniform sampling base.

However, it is to be noted that in the last test (No. 9) different monitors were used at the two laboratories. It is suggested that every effort be made to arrange for TITL to use the same monitor cigarettes as the FTC laboratory and that great care be used to assure that they are well mixed and that a full comparison be made after each test.

Sincerely,



Herbert Arkin

HA:koc

PM3001013723